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PUBLIC MEETING NOTICE:	**CONTROLLED SUBSTANCE COMMITTEE**
DATE AND TIME:	**Wednesday, June 22, 2016 at 9:00 a.m.**
PLACE:	**Buena Vista Conference Center, Buck Library, First Floor, 661 S. DuPont Highway, New Castle, Delaware 19720**
APPROVED:	August 24, 2016

MEMBERS PRESENT
Luis Garcia, Jr., DPM, Podiatric Representative, Vice President
Philip Kim, M.D., Medical Representative
Jo Ann M. Baker, DNP, RN, FNP-C, Nursing Representative
Herb E. Von Goerres, R.Ph., Pharmacy Representative
Alex Zarow, R.Ph., Pharmacy Representative
Mark Hanna, Public Representative

MEMBERS ABSENT
Michael Kremer, DMD, Dental Representative, President
Art Jankowski, VMD, Veterinary Representative
Stephen Ruggles, PA-C, PA Representative

DIVISION STAFF/DEPUTY ATTORNEY GENERAL
David W. Dryden, R.Ph., J.D., Director, Office of Controlled Substances
Christine Mast, Administrative Specialist III
Eileen Kelly, Deputy Attorney General
Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT
Hooshang Shanehsaz, R.Ph.
M J Peta

CALL TO ORDER
Mr. Von Goerres called the meeting to order at 9:04 am.

REVIEW AND APPROVAL OF MINUTES
A motion was made by Ms. Baker, seconded by Mr. Hanna, to approve the minutes for April 27, 2016. The motion was unanimously carried.

UNFINISHED BUSINESS
Deliberations – Amended Regulation 4.10.1, 4.10.1.5
Ms. Kelly provided the committee the amended regulation. There was no written or public comment received. A motion was made by Dr. Garcia seconded by Dr. Kim to accept the proposed regulations. The motion carried unanimously.

PRESIDENT'S REPORT
None

NEW BUSINESS

DIRECTOR'S REPORT

Mr. Dryden reported that he attended a meeting at NABP Annual Meeting.

Case/Diversion Review

There have been sterile fill issues that have been brought to the attention of the Board of Pharmacy which has resulted in an inspection in conjunction with the FDA. Mr. Dryden continues to work with the FDA on this issue and has attended four meetings since 2012 regarding 795/797.

Mr. Dryden is also working with the Veterinary community regarding office use and the issues the FDA Guidance on office use has created in the veterinary community. He has met with the DVMA and the Board of Veterinary Medicine.

Mr. Dryden also spoke with Senator Carper's office regarding the denial of dispensing of prescribed medications by a pharmacist. He explained that pharmacists deny prescriptions are because it's a questionable opioid prescription; the prescription is fraudulent or has been altered. He also explained that the pharmacist staff utilizes the state PMP to assist with the prevention of diversion and the Tamper Resistant Prescription pads have also helped with this process.

Mr. Dryden stated that Ms. Kelly has been very instrumental in working with the draft Safe Opioid Prescribing regulation.

Mr. Dryden reported that he also assisted in a criminal investigation involving harness racing.

Ms. McCreary had no report.

Current Events

President Obama Announces Administration's Actions to Combat Drug Abuse at National Rx Summit
President Barack Obama attended the National Rx Drug Abuse and Heroin Summit in Atlanta, GA, on March 29, 2016, and announced actions his Administration is taking to further expand access to treatment, prevent overdose deaths, and increase community prevention strategies. The expanded initiatives will include public and private sector actions taken to address the epidemic, building on efforts announced in October 2015.

HHS Proposes Increasing Buprenorphine Patient Limit for Medication-Assisted Treatment
With the goal of expanding access to medication-assisted treatment (MAT), United States Department of Health and Human Services (HHS) has proposed a rule that would permit qualified physicians to prescribe buprenorphine, the opioid use disorder treatment medication, to as many as 200 patients. Under current regulations, physicians who are certified to prescribe buprenorphine for MAT can only prescribe up to 30 patients initially and after one year can request authorization to prescribe up to a maximum of 100 patients. Substance Abuse and Mental Health Services Administration Principal Deputy Administrator Kana Enomoto states "there are long patient waiting lists for prescribers who have reached the 100 patient limit." Buprenorphine is a Food and Drug Administration (FDA)-approved drug used as part of MAT, a comprehensive way to address the recovery needs of individuals that combines the use of medication with counseling and behavioral therapies to treat substance use disorders.

PMP Review

Mr. Dryden presented educational material titled "Patient Risk Measures for Controlled Substance Prescriptions in Delaware, 2012-2015" provided by Ms. Samantha Nettesheim, PMP Pharmacist Administrator, that she would like to send to all practitioners. A motion was made by Ms. Baker seconded by Mr. Von Goerres to send this material to all practitioners. The motion unanimously carried.

Dr. Kim expressed concern with an issue of practice with regards to illicit use of marijuana and the inability to know who has been prescribed medical marijuana and the diagnosis for such. This could present issues when drug test are completed and marijuana is present. He would ask that the committee

Review of Draft – Syringe Law §4762

Ms. Kelly provided a draft of proposed statute changes to §4762 Syringe Law which removes the need for a prescription. The committee reviewed these changes. A motion was made by Dr. Garcia seconded by Ms. Baker to approve this draft statute change and have Ms. Kelly put this into bill format. The motion unanimously carried.

COMMITTEE REPORTS

Medical Examiner's Report
No report.
DEA Report
No report
Substance Abuse Report
No Report
Law Enforcement Report
No Report
Regulatory Committee Report
No Report
Legislative Committee Report
No Report

COMMITTEE CORRESPONDENCE

GW Pharmaceutical, Alice Mead, Vice President – sent a letter regarding the Epidiolex, a pure cannabidiol (CBD) investigational product used as a potential anti-convulsive treatment for children. There is no effective high received by the patient. GW will be filing a new application with the FDA within the next year seeking approval for the use of this drug. This is currently available outside of the United States.

Confronting a Crisis: An Open Letter to America's Physicians On Opioid Epidemic

OTHER BUSINESS BEFORE THE BOARD

None

PUBLIC COMMENTS

Mr. Shanehsaz, R.Ph. stated that the syringe law changes were brought to the Board of Pharmacy attention throughout the last several months. Current statute does not allow dispensing without a prescription. However, less than 10 states allow dispensing without a prescription. The Board of Pharmacy felt it necessary to request review of the statute to better suit the needs of the public.

Dr. Philip Kim stated that the Delaware Medical Society has concerns in relation to the acute care 7 day limit placed on prescribing in the "Safe Opioid Prescribing" regulations changes. They addressed these concerns in their comments during the written comment period.

EXECUTIVE SESSION

None

NEXT SCHEDULED MEETING

The next regular meeting will be held on August 24, 2016 at 9:00 am at the Buena Vista Conference Center, Buck Library.

ADJOURNMENT

A motion was made by Dr. Garcia, seconded by Dr. Kim, to adjourn the meeting at 9:40 am. The motion carried.

Respectfully submitted,

Christine Mast
Administrative Specialist III
Office of Controlled Substances